Electronic Submission and Review
Frequently Asked Questions — Submitter
December 11, 2002

CD Creation

Which test guideline numbers, OPP or OPPTS harmonized (e.g. 81-1 vs. 870.1100), do I use when naming folders on the CD?

Use which ever guideline is appropriate to the study. If either is applicable, use the harmonized one.

Do any typefaces help in the OCR process?

San serif fonts such as Arial apparently OCR more accurately than Serif fonts (eg. Times). Keep in mind, however, that f there is the ability to select the typeface for the study prior to printing, then it may be possible to create the PDF directly from the electronic source eliminating the need for the OCR process.

When creating the CD, what type of CD should I use?

Any type of recordable CD should be suitable. Avoid the use of multi-use CD-RW discs that may be recorded over.

Submission Process

Do I need to submit paper copies before the electronic copies?

Yes, the MRID number must be assigned prior to the creation of the CD.

Does the PDF copy of the study need to include signatures?

*No. The paper copy is maintained as the official copy and must include signatures and pass other PR Notice 86-5 formatting requirements. The purpose of the PDF copy, even though it must conform to other PRN 86-5 requirements, is to expedite the review process and hence signatures are not required. The submitting company, must however, include with the CD a properly filled out **Certification with Respect to Data Integrity** form certifying that the electronic copies are the same as the paper copies.*

Supplemental Files

For which studies should I submit supplemental files?

Standard formats have been developed for four toxicity: Chronic/subchronic toxicity; Delayed neurotoxicity; Multi-generation reproduction; and Prenatal developmental toxicity. These formats are interim guidance since the use of supplemental files is still in the pilot phase. With other studies where there exists large amounts of tabular data and statistical analysis by EPA staff may be desirable, the submission of supplemental files (SAS transport or Excel) may be useful but no standard format is available at this time.

What format should the supplemental files be in?

As specified in the guidance, SAS transport version 5 should be used for the supplemental files. Where SAS transport is impractical, spreadsheets may be used provided that they contain no complex formulas. Keep in mind that the submission of supplemental files is currently in the pilot stage and may be subject to changes as additional information is obtained.

Study Layout

The guidance specifies Times New Roman as the preferred typeface. Is Arial OK?

Yes. However, when using uncommon fonts, make sure that the fonts are "embedded" into the PDF during creation.

What are uncommon fonts?

Acrobat specified the "Base 14 Fonts" as Courier (bold, boldoblique, oblique), Helvetica (bold, boldoblique, oblique), Symbol, Times (bold, bold italic, italic, Roman), and ZapfDingbats and are known to Acrobat innately. Any fonts other than these 14 should be embedded.

The guidance specifies to use 12 point type for tables. Can a smaller font be used?

Yes, when the tables will be unwieldy using the larger font, it is OK to use a smaller font. Avoid, however, anything smaller than 8 point.